

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

This document relates to:  
*All Actions*

No. 1:19-md-2875-RBK-KMW

Hon. Robert B. Kugler

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO ZHP'S OBJECTION  
TO SPECIAL MASTER ORDER NO. 28 DENYING ITS MOTION FOR A  
PROTECTIVE ORDER PRECLUDING THE DEPOSITION OF BAOHUA CHEN**

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## **INTRODUCTION**

Special Master Vanaskie considered a substantial record and correctly denied ZHP's motion for a protective order, as to which ZHP carried the high burden of proof, in its effort shield Baohua Chen from providing deposition testimony:

**[T]his is not a case that involves the routine day-to-day operations of ZHP.** Nor does this case present a garden-variety tort claim. It is a case that concerns the alleged contamination of a popular blood pressure pharmaceutical produced by a leading player in the world-wide market. And it is not a case that raises a claim of an isolated instance of contamination; it concerns the manufacturing process that may have resulted in wholesale contamination of the product. **This is the kind of case that one would expect a company's leader would be playing a leading role, and Plaintiffs have adduced evidence of such a role being played by Mr. Chen. *The evidence cited by Plaintiffs* is indeed sufficient to rebut the presumption that, as an 'apex' witness, Mr. Chen lacks unique knowledge of the nitrosamine contamination and ZHP's response to it. .... Plaintiffs have shown that Mr. Chen may have unique knowledge that they have been unable to obtain from numerous witnesses deposed thus far.**

([ECF 1330, p. 6](#) (emphasis added)).

ZHP's motion fails to submit any compelling argument or analysis, mischaracterizing and minimizing the record relied on by Judge Vanaskie. Review of this record, and consideration of the mostly inapplicable cases cited by ZHP (to the extent applicable the cases support Plaintiffs' position), demonstrates that Judge Vanaskie correctly and thoroughly exercised his discretion, requiring denial of ZHP's motion.

### **PROCEDURAL HISTORY**

Plaintiffs included Baohua Chen on their final list of designated custodians, which was subject to extensive meet and confers and prior argument before the Court. In an eleventh-hour request, ZHP emailed the Court an hour before the December 18, 2019 case management conference to object to his inclusion as a custodian for the first time. ([12/18/2019 Tr. 6:17-7:18, 9:11-20](#)). Plaintiffs consequently had to scramble to oppose the objection. In securing the ruling that he would not be included at that time (a ruling later superseded by a ruling adding Mr. Chen as a custodian based on the later developed record), ZHP assured the Court that “[h]e is not involved in any of the manufacturing, testing, regulatory, quality affairs, quality assurance, quality control functions at the company,” and the Court sustained its objection at that time. (*Id.* at 7:10-12, 24:16-19). However, the Court held open the Plaintiffs’ right to later seek modification of this ruling based on a more fulsome record: “I could be proven wrong in the future. If there is evidence in that regard, so be it.” (*Id.* at 24:14-15). The Court added:

I'll make it clear. The Court is not ruling at this time whether or not Mr. Chen is an appropriate deponent. That's a completely different evaluation that the Court has to consider at the relevant time. If defendant [sic] wants to depose Mr. Chen, we'll deal with the issue at that point. But in no way, shape, or form should the Court's ruling as to whether or not Mr. Chen is an appropriate custodian be deemed as a ruling as to whether or not he may be deposed in the case.

(*Id.* at 24:20-25:2).

A year later Judge Schneider ruled that Mr. Chen was a proper deponent. ([ECF 704](#)). He also granted Plaintiffs “leave to file a motion requesting production of Mr. Chen’s custodial file” and ZHP leave to file a motion for a protective order to preclude the deposition based on a “sufficient deposition record.” (*Id.*). The Parties consequently scheduled his deposition for May 31, 2021.

On April 27, 2021, and in light of recent deposition testimony, Plaintiffs asked the Court to order the production of Mr. Chen's custodial file. ([ECF 1189](#)). After allowing ZHP to brief its opposition in full, the Court agreed with Plaintiffs and ordered ZHP to produce Mr. Chen's custodial file. ([ECF 1315](#)).

On May 17, 2021, ZHP filed its motion for a protective order to preclude the deposition of Mr. Chen. ([ECF 1247](#)). On June 22, 2021, Special Master Vanaskie denied this motion. ([ECF 1330](#)). Three days later, ZHP informed Special Master Vanaskie that it was considering a challenge to his denial "that would have to be done I believe by July 13th." ([6/25/2021 Tr. 6:23:23-25](#)). Special Master Vanaskie consequently postponed the scheduling of Mr. Chen's deposition to allow this motion to be filed and ruled upon. (*Id.* at 11:1-8). ZHP filed its objection on July 13, 2021. ([ECF 1386](#)).

**BAOHUA CHEN IS THE LINCHPIN OF  
THE ZHP ORGANIZATION AND ITS CONTAMINATED VALSARTAN**

ZHP's motion fails to contend with the record established before Special Master Vanaskie showing Baohua Chen's central role in the ZHP organization as well as the development, manufacture, sale, and recall of its contaminated valsartan. According to an organization chart, Baohua Chen is the CEO of ZHP and Shanghai Syncores. (ZHP00076700, Ex. A hereto; ZHP00076708, Ex. B hereto).<sup>1</sup> Importantly, Syncores is ZHP's wholly-owned research entity that in 2011, developed the zinc chloride manufacturing process that resulted in contamination of valsartan with NDMA. The organization chart also states that "[a]ll the VP or directors are reported to Baohua Cheng [d]irectly," and shows that Mr. Chen is the linchpin between ZHP, Shanghai Syncores, Prinbury, Huahai US, Princeton, and Solco. (ZHP00076709, Ex. B hereto).

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<sup>1</sup> All discovery materials relied on in this brief were relied on in Plaintiffs' original opposition to ZHP's motion for a protective order precluding Baohua Chen's deposition. For the Court's convenience, Plaintiffs have attached them to this brief as well.

Mr. Chen is not just a figurehead, he has direct technical knowledge and training. According to ZHP's Drug Master File (DMF) for valsartan, which was filed with the FDA, [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED].<sup>2</sup> Mr.

**Chen has a Master of Science in Chemical Engineering.** (ZHP00004937 (emphasis added), Ex. F hereto). ZHP's valsartan DMF also states, [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]. As already mentioned, all vice presidents or directors report to Mr. Chen directly; thus, as the **"General Manager,"** he effectively leads all of ZHP's departments and is responsible for coordinating and synthesizing their disparate activities. He managed 3,800 employees as of May 2014. (ZHP00004937, Ex. F hereto).

During FDA inspections, Mr. Chen directly told the FDA that he "has the ultimate authority at the firm and takes **full responsibility for the company's operations.**" (PRINSTON00083647

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<sup>2</sup> ZHP criticizes Special Master Vanaskie's reliance on Exhibit C, which is similar to Exhibits D and E, in his decision to deny its motion. ([ECF 1386-1, p. 12-13](#)). However, ZHP overlooks that this is the DMF for its valsartan. A DMF is the regulatory filing that an API manufacturer files with the FDA in order to allow finished dose manufacturers to incorporate its API into its applications for FDA approval. See FDA, *Drug Master Files (DMFs)*, <https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs>. Special Master Vanaskie and this Court should give significant weight to the claims made in such a filing.

(emphasis added), Ex. G hereto).<sup>3</sup> Not surprisingly, Mr. Chen participated in at least seven FDA inspections, in August 2013, May 2014, March 2015, November 2016, June 2017, January 2018, and June 2019. At the August 2013 inspection, the Vice General Manager of Quality Assurance said that he reported directly to Mr. Chen. (PRINSTON00083002, Ex. H hereto). After that inspection, Mr. Chen “promised to correct/evaluate all discussion items and to expand the corrections to any related issues.” (PRINSTON00083010, Ex. H hereto). The March 2015 inspection reports identified Baohua Chen as the “most responsible person.” (PRINSTON00083028, 31, Ex. I hereto). The May 2014, November 2016, and January 2018 inspection reports state that all FDA correspondence should be addressed to Mr. Chen. (PRINSTON00074128, Ex. J hereto; PRINSTON00081551, Ex. K hereto; PRINSTON00081574, Ex. L hereto). The record is clear that Mr. Chen played a central role at ZHP and that he communicated directly with the FDA.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>3</sup> ZHP also criticizes Special Master Vanaskie for relying on this document in his decision. ([ECF 1386-1, p. 14](#)). It claims, “This is a truism for all presidents/CEOs” and adds that the document does not “identify any specific role played by Mr. Chen in creating or implementing corrective actions in response to the FDA’s 483 letter.” (*Id.* at 14-15). However, the document clearly states that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Consistent with the strategy spearheaded by Mr. Chen, ZHP has told the FDA that it changed to the contaminating zinc chloride manufacturing process in order to lower the cost of its valsartan and dominate the world market as a result. (PRINSTON00162373, Ex. U hereto). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Mr. Chen was also intimately involved with ZHP's recall of Valsartan. ZHP's "Protocol of Valsartan API Recall (Foreign grade)" lists Mr. Chen as the first member of the "Recall Group," and that group does not include Jun Du, who is the CEO of all three of ZHP's U.S. subsidiaries,

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<sup>4</sup> ZHP inexplicably criticizes Special Master Vanaskie's reliance on Exhibit O in his decision. It states, "Plaintiffs' point to nothing in these emails that demonstrates unique knowledge of ZHP's market share or pricing of valsartan, as such market share or pricing pertain, if at all, to the alleged nitrosamine contamination at issue here." (ECF 1386-1, p. 13). [REDACTED]

Second and relatedly, ZHP takes issue with Special Master Vanaskie's reliance on Exhibit U (discussed above in the next sentence), which explains that ZHP adopted the contaminating manufacturing process in order to lower the cost of its valsartan and increase its market share. The Court should reject ZHP's criticisms, which ignore or mischaracterize the contents of these documents.

which are all based in New Jersey. (ZHP00494048, Ex. V hereto). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]<sup>5</sup> [REDACTED]

[REDACTED]

---

<sup>5</sup> This is the last Exhibit that ZHP criticizes Special Master Vanaskie for relying on. [REDACTED]

[REDACTED]

[illegible]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Contrary its briefing, ZHP's witnesses have confirmed the above narrative without being able to fill in the gaps that only Baohua Chen can. For example, ZHP has repeatedly claimed that Jun Du could provide the same information as Baohua Chen. (*See, i.e.*, [5/03/2021 Tr. 43:18-22](#)). ZHP even asked for an extension to file its motion in order to include his testimony and ultimately filed a supplemental brief on this basis. (*Id.* at 43:7-12; [ECF 1295](#)). **Yet, Jun Du's deposition only supports Plaintiffs' need for the deposition of Mr. Chen. Despite bearing the burden on this motion, requesting an extension to file it, and then filing a supplemental brief afterwards, ZHP did not ask Mr. Du a single question about Mr. Chen during his deposition.** Moreover, Jun Du painted himself as so remote from the ZHP day-to-day operational decisions that **he does not have an office in China.** (5/27/2021 Tr. of Jun Du Dep. 19:1-3 (emphasis added), Ex. MM hereto). In addition, Jun Du actually sought to distance himself from ZHP's August 26, 2018 response to the FDA's 483 notifications arising from the July and August FDA inspections, **which he signed**, claiming that he did not read the letter before he signed it—in large part because he claimed not to have knowledge of the GMP issues discussed (which is an area of Mr. Chen's authority as set forth above):

Q. Exhibit 430 is a letter that you signed in your capacity as executive vice president of ZHP, correct?

A. That is correct. I signed this letter on behalf of ZHP.

Q. Did you read the letter before you signed it?

A. **I did not completely review this letter.** This letter was completed by the QA department, QC department, technology department, and analytical department of ZHP. As the contact person for the FDA, I signed this letter on behalf of our company.

Q. When you say you did not completely review this letter, is it your testimony that before you signed the letter, which you knew was going to the FDA, you didn't read the entire letter?

A. That is correct, I did not. **I trust in the professional expertise of our team. Besides, I did not have the GMP knowledge at that time.**

(5/27/2021 Tr. Jun Du Dep. 57:19-60:10 (emphasis added), Ex. MM hereto).

As already explained, all departments report directly to Mr. Chen, ZHP's General Manager. Jun Du even admitted that his title as ZHP's Executive Vice President was temporary, and for the convenience of Mr. Chen. (*Id.* at 34:5-8 (stating, "Those were merely interim assignments. **Whenever Baohua Chen as the general manager was unavailable, someone was needed for the coordination.**" (emphasis added))). As set forth above, Mr. Chen is the person who coordinated the QA team, the QC team, and the RA team—all of which he leads independently and directly—in their response to the July and August 2018 FDA inspection. Plaintiffs are thus entitled to question Mr. Chen on this letter as well as ZHP's valsartan more generally.

ZHP also claims that the deposition of Min Li, its Vice President of Analytical Operations, obviates the need for Baohua Chen's deposition. ([ECF 1386-1, p. 17](#)). However, that testimony supports the need for the deposition of Mr. Chen. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The compelling information learned during the deposition of Min Li is an overlay definitively refuting ZHP's

consistent and deliberate understatement of Mr. Chen's involvement in relevant corporate activities.

ZHP also relies on the testimony of Jucai Ge, its Director of API Quality Assurance at the Chuannan Site. ([ECF 1386-1, p. 15](#)). Again, Plaintiffs asked the following line of questions which demonstrated the complete lack of credibility in ZHP seeking to hold up Jucai Ge's deposition as sufficient to meet its high burden on this motion:

Q. Ms. Ge, you just testified that all of the chairman of the company, Bao[hua] Chen, knows is from the reports we provided to him.

How do you begin to purport to know what knowledge Mr. Chen has about NDMA?

**A. He organized a meeting or meetings on the topic of NDMA in valsartan. He did organize such a meeting or meetings.**

Q. So –

A. During the meeting we all reported or all of the departments reported to him regarding the progress of the investigation and -- and -- and other information.

Q. During the meetings, what did Mr. Chen say to you?

**A. I can't describe to you the gist of his statement to you. I cannot recall the original wording of his and I cannot recall which meeting he made such statements in.**

\* \* \*

Q. Please give me your best estimate as to how many meetings you participated in with Mr. Chen regarding NDMA?

**A. I don't remember exactly how many times.**

Q. Give me your best estimate.

**A. My estimate would not be that accurate.**

Is that okay?

Q. Yes.

A. Well, I would just provide a rough estimate.

Q. Yes, please pro -- provide it right now.

A. For all kinds of meetings where NDMA was mentioned, I believe it's five meetings also.

Q. Okay. Who attended these roughly five meetings with Mr. Chen regarding NDMA?

A. **I don't recall who specifically those attendees were**, but typically I would attend for the meetings I was there and a QP would be there, people from QC would be there. So it's pretty much people from those department, although the attendees would vary. They would be there to follow up with the progress and sometimes vice president Min Li -- spelled as M-i-n, last name L-i -- would also be there, but I don't recall specific attendees.

Q. Did you take notes during these approximately five meetings with Mr. Chen?

A. There was nothing to take notes for. **I never take notes.** All he said was, Hey, hurry up or do it according to the GMP requirement. It's nothing worth taking notes for.

\* \* \*

Is it part of your job description to know what Mr. Chen does from -- on a day-to-day basis?

A. **It -- it is not.**

(4/30/2021 Tr. of Jucai Ge Dep. 368:11-371:21, Ex. OO hereto). It is telling that ZHP chose Ms. Ge with her less than helpful recollection and knowledge as the one witness to ask about Mr. Chen's knowledge and role in this case.

Hong (Eric) Gu's deposition does not help ZHP either. Mr. Gu only started working at Syncores in 2014, and Syncores finished developing the zinc chloride process in 2011. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Only Mr. Chen can tell what he knew, how and why he set policy and made other day-to-day decisions. This is just another example of a document showing that Mr. Chen's knowledge is an important part of the valsartan story.

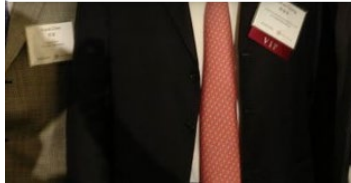
According to ZHP, "Plaintiffs cannot reasonably allege that Mr. Chen's testimony as to the interrelationship between the various ZHP entities would be unique given that Plaintiffs have already deposed Jun Du, Eric Gu, Eric Tsai, Hai Wang, and Xiaodi Guo, all of whom also hold senior positions in multiple ZHP Party entities, on this subject." ([ECF 1386-1, p. 13 n.8](#)). This argument is obvious evasion. Baohua Chen is the linchpin of the ZHP Organization leading all of its departments and playing an active role in its subsidiaries, especially Shanghai Syncores, where he is CEO. Plaintiffs understand how these departments and subsidiaries are linked (by Baohua Chen), but need to depose Baohua Chen on how and why he coordinated and led all these departments and entities to develop, manufacture, sell, and recall nitrosamine contaminated valsartan throughout the world, including the United States. In fact, Hai Wang, the Vice President of Prinston and President of Solco, testified that [REDACTED]

[REDACTED]

[REDACTED] The Facebook page of PrinJohnson, an intermediate holding company between Huahai US and Prinston, which in turn owns Solco, focuses on Mr. Chen's involvement in these operations:



Baohua Chen Chairman of PrinJohnson



([PrinJohnson's Facebook Page](#)).



([PrinJohnson's Facebook Page](#)). Moreover, Plaintiffs have cited numerous documents above establishing that Hai Wang relied on Mr. Chen to determine the price of Valsartan and balance that price with his target for ZHP's market share. Once again, all major decisions point to Mr. Chen, whether they are communications with the FDA, the product recall, or the pricing of ZHP's valsartan.

Peng Dong's evasive testimony regarding Mr. Chen also shows that Mr. Chen was substantively involved:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Thus, Peng Dong's deposition further supports Plaintiffs' need for Mr. Chen's deposition.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Xiaodi Guo's testimony regarding Mr. Chen was also extremely limited. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] testimony does not help ZHP on this motion, and the reliance on this testimony is puzzling.

Mi (Karen) Xu was similarly unable to answer the few questions asked by Plaintiffs' counsel about Mr. Chen in her deposition. Notes *from her custodial file* referred to consulting with "Chen & Chen" regarding potential settlement and compensation for a customer as result of the contamination of ZHP's valsartan, but Ms. Xu could not identify "Chen & Chen," as she could not "even confirm who generated this document." (5/21/2021 Tr. of Mi (Karen) Xu Dep. 140:3-12, Ex. LL hereto). As already established, Mr. Chen was heavily involved with addressing customer concerns after the discovery of the contamination.

In its brief, ZHP summarily describes Minli Zhang's deposition but does not explain how Mr. Chen's testimony would be duplicative. ([ECF 1386-1, p. 15](#)). Plaintiffs note that Ms. Zhang did not discuss Mr. Chen during her deposition, and ZHP did not ask her any questions about Mr. Chen. Inclusion of this reference in the motion, as well as the references to obscure testimony from other witnesses, is mere filler on ZHP's motion, and proves nothing that would help ZHP to meet its burden.

On this record, ZHP cannot present any reasonable argument to preclude the deposition of Baohua Chen. He was involved at every point in the process, and has direct knowledge from all corners of the company that Plaintiffs cannot learn or confirm from other sources. And Mr. Chen has to account for key matters he was at the heart of, and confirm what he knew and when, including but not limited to the inadequate risk assessments of the TEA and zinc chloride

processes, the decision to develop the contaminating zinc chloride process, the decision to hide the contamination in order to maximize corporate profits, and the grudging disclosure only when Novartis forced ZHP to do so.

## LEGAL ARGUMENT

### I.

#### STANDARD OF REVIEW

Numerous courts have concluded that “a special master’s ruling on discovery disputes [are] procedural and therefore subject to an abuse of discretion standard,” including a “motion to quash certain deposition notices.” *Engage Healthcare Communications, LLC v. Intellisphere*, No. 12–787 (FLW)(LHG), 2017 WL 6539242, at \*2 n.1 (D.N.J. Dec. 21, 2017) (citing Fed. R. Civ. P. 53(f)(5); *Nippon Steel & Sumitomo Metal Corp. v. Posco*, 2014 WL 1266219, at \*1 (D.N.J. 2014)) (Ex. TT hereto). ZHP relies on *Valeant Pharmaceuticals International, Inc. v. AIG Insurance Co. of Candana* for the proposition that “where a special master’s order interprets cases and applies them to rule whether certain discovery must be produced, a special master makes ‘legal determinations that are subject to *de novo* review.’” ([ECF 1386-1, p. 8](#) (quoting *Valeant*, No. 18-493 (MAS)(LHG), 2020 WL 7768405, at \*4 (D.N.J. Dec. 30, 2020))). Plaintiffs note that Judge Lois H. Goodman authored both *Engage* and *Valeant*. In the latter case, Judge Goodman focused on the special master’s determination “that certain documents were not relevant to Defendants’ assertion of a defense” and “therefore need not be produced.” *Id.* at \*4.

Here, as in *Engage*, Special Master Vanaskie made a discretionary determination that ZHP had not met its burden on its motion to quash the deposition of Mr. Chen. He did not determine the contours of Plaintiffs’ claims or Defendants’ defenses in reaching his decision. The Court should therefore apply the abuse of discretion standard.

## II.

### **BAOHUA CHEN'S DEPOSITION SHOULD PROCEED AS ORDERED**

As Special Master Vanaskie recognized, Federal Rule of Civil Procedure 26(c)(1) states that the Court “may, *for good cause*, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense.” ([ECF 1330, p. 1](#) (emphasis added)). ZHP has a high burden of proof on this motion: “Good cause, in turn, requires the movant to demonstrate ‘that [the discovery] will work *a clearly defined and serious injury* to the party seeking closure.’” *Otsuka Pharm. Co. v. Apotex Corp.*, 310 F.R.D. 256, 259 (D.N.J. 2015) (quoting *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir.1994) (emphasis added)). “[T]he burden rests with the party seeking a protective order.” *Id.* at 260 (citing *Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986) (emphasis added)) (denying a motion for a protective order to preclude a deposition). When it granted ZHP leave to file this motion for a protective order, the Court clearly stated, “It’s his [(ZHP’s counsel’s)] motion for protective order, so it’s his burden, of course.” ([12/22/2020 Tr. 48:1-2](#)). **“Broad allegations of harm, unsubstantiated by specific examples, however, will not suffice.”** ([ECF 1330, p. 2](#) (quoting *Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995) (emphasis added))). Importantly, ZHP has never provided the Court with a declaration specifically defining any alleged harm that would stem from the deposition of Mr. Chen.<sup>6</sup>

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<sup>6</sup> ZHP asks the Court to take judicial notice of Mr. Chen’s membership in the National People’s Congress of the People’s Republic of Chinese. ([ECF 1386-1, p. 2 n.1](#)). It also raises questions about whether Mr. Chen can even obtain a travel permit to attend a deposition. (*Id.* at 9, n.6). Neither of these arguments were raised in support of its original motion before Special Master Vanaskie and they should be disregarded accordingly. In fact, when the Parties met and conferred regarding this “issue” on April 23, 2021, ZHP’s counsel admitted he could not explain what Mr. Chen even did as a member of the National People’s Congress. Because the Court had already ordered Mr. Chen’s deposition and the Parties had scheduled it for May 31, 2021, Plaintiffs were also quite surprised that Mr. Chen had never obtained a permit to travel for his deposition. In any event, that is not at issue on this motion.

**A. The “Apex Doctrine” Is Overstated and Misapplied by ZHP**

Instead of acknowledging and addressing its burden on its motion for a protective order from a deposition already ordered and scheduled, ZHP overemphasizes and mischaracterizes the “apex doctrine.” Quoting one of the five unpublished, distinguishable cases relied on by ZHP in its initial brief, Special Master Vanaskie correctly concluded, “The apex doctrine is merely a tool for guiding the Court’s analysis in determining whether to limit discovery under Rule 26(b)(2)(C) because the discovery can be obtained from some other source that is more convenient, less burdensome, or less expensive.” ([ECF 1330, p. 7-8](#) (quoting *United States ex rel. Galmines v. Novartis Pharm. Corp.*, No. CV 06-3213, 2015 WL 4973626, at \*2 (E.D. Pa. Aug. 20, 2015))).

In fact, **the published federal appellate decision most directly addressing the “apex doctrine” has rejected the broad sweep argued for by ZHP.** In *Serrano v. Cintas Corp.*, the Sixth Circuit “conclude[ed] that the magistrate judge erred as a matter of law in relying on ‘apex doctrine’ to grant the protective order.” 699 F.3d 884, 902 (6th Cir. 2012). The court explained:

[W]hile we sometimes have considered the need for the deposition—i.e., its potential to result in relevant testimony—in reviewing the grant or denial of a protective order, **we have not abandoned the requirement that one of the harms listed in Rule 26(c)(1)(A) must be specified in order to warrant a protective order.** Even in cases where we have considered extensively a corporate officer's knowledge and, thus, capacity to provide information relevant to the case, **we have declined “to credit a [corporate officer's] bald assertion that being deposed would present a substantial burden,” and still required the corporate officer to meet Rule 26(c)(1)'s requirements.**

*Id.* at 901 (emphasis added). This all follows from Federal Rule of Civil Procedure 26. *Id.*

ZHP’s reliance on *Salter v. Upjohn Company*, 593 F.2d 649 (5th Cir. 1979), and *Thomas v. Int’l Bus. Machines*, 48 F.3d 478 (10th Cir. 1995), as examples of published federal appellate decisions “addressing the ‘apex doctrine,’” is not helpful to its position, applying standard criteria to a motion for a protective order. ([ECF 1307, p. 6](#)). In *Salter*, the Fifth Circuit ruled: “We do not

interpret this ruling as totally prohibiting plaintiff from taking [the president's] deposition. Rather, the trial judge was merely exercising the broad discretion that this court has long recognized he has in controlling the timing of discovery.” 593 F.2d at 651. The Fifth Circuit then concluded, **“Of course, if after taking the other depositions, plaintiff was not satisfied and again properly gave notice of or requested taking Dr. Hubbard's deposition, the judge probably should have allowed the deposition.** After the first protective order, however, plaintiff never again properly raised the issue in the trial court.” *Id.* (emphasis added).

*Thomas* is not any more helpful for ZHP. There, the plaintiff noticed the deposition of IBM's chairman six days before the end of the already extended deadline for discovery, and violated the Local Rules in terms of timing and location. 48 F.3d at 482-83. The Tenth Circuit also noted that “IBM submitted an affidavit from Akers in which he testified that he lacked personal knowledge of Thomas and was unaware of her age, her performance ranking, any work evaluations that she might have received, or that she even worked for IBM.” *Id.* None of these grounds for quashing a deposition exist in this case, and they are all universally applicable to any deposition, not just “apex depositions.” Special Master Vanaskie correctly held, “There is, however, no *per se* rule barring depositions of senior executives, and ‘[i]t is rare for a court to issue a protective order that prohibits a deposition.’” ([ECF 1330, p. 7](#)).

#### **B. The Purported “Apex Doctrine” Does Not Shield Baohua Chen**

As the Sixth Circuit noted, “the ‘apex doctrine’ is built on the false foundation that ‘harassment and abuse’ are ‘inherent’ in depositions of high-level corporate officers and therefore allows such depositions to be barred absent ‘a showing that the individual possesses relevant evidence which is not readily obtainable from other sources.’” *Serrano*, 699 F.3d at 901. Before Special Master Vanaskie's decision, Judge Schneider had already established that the Court was “not that sympathetic to the apex argument,” explaining:

[W]e've all been through this in many different cases. If they're deposing a CEO because he may have signed a form contract and he doesn't have any personal knowledge of what happened, **but here, we have a situation where plaintiffs are seeking to depose the gentleman in large part because of the information he gains when he was, in my words, in a front-line position.**

([12/22/2020 Tr. 40:4-5, 44:2-8](#) (emphasis added)). Special Master Vanaskie rightly elaborated on this line of reasoning:

[T]his is not a case that involves the routine day-to-day operations of ZHP. Nor does this case present a garden-variety tort claim. It is a case that concerns the alleged contamination of a popular blood pressure pharmaceutical produced by a leading player in the world-wide market. And it is not a case that raises a claim of an isolated instance of contamination; it concerns the manufacturing process that may have resulted in wholesale contamination of the product. **This is the kind of case that one would expect a company's leader would be playing a leading role, and Plaintiffs have adduced evidence of such a role being played by Mr. Chen.**

([ECF 1330, p. 6](#) (emphasis added)). ZHP's arguments are not faithful to the record, which fully supports Judge Vanaskie's decision.

### C. ZHP Has Not Met Its Burden Under Rule 26

ZHP has not submitted a declaration from Mr. Chen establishing, with the necessary level of specificity, how his deposition would cause "annoyance, embarrassment, oppression, or undue burden or expense." Fed. R. of Civ. Proc. 26(c)(1); *see also Serrano*, 699 F.3d at 901; *Otsuka Pharm.*, 310 F.R.D. at 259 (citing *Pansy*, 23 F.3d at 786). This is likely because the record demonstrating Mr. Chen's involvement is overwhelming—leaving ZHP to hope for the Court to overlook this requirement.

Given the record provided by Plaintiffs in opposition to ZHP's motion, Special Master Vanaskie correctly found, "***The evidence cited by Plaintiffs is indeed sufficient to rebut the presumption that, as an 'apex' witness, Mr. Chen lacks unique knowledge of the nitrosamine contamination and ZHP's response to it.*** .... The evidence suggests that Mr. Chen was not a

detached manager, but an active participant in matters at the core of this case.” ([ECF 1330, p. 6-7](#) (emphasis added)). Plaintiffs clearly proved Mr. Chen has unique knowledge of the case.

ZHP spends most of its effort attempting to deflect from the merits. This includes isolating the documents that Special Master Vanaskie specifically relied on, instead of grappling with the record in its entirety. ZHP then argues this artificially limited record fails to support his decision. **However, ZHP glaringly omits that twenty-six of the thirty-eight exhibits to Plaintiffs’ opposition were designated as confidential and thus filed under seal.** As here, in prior orders, Special Master Vanaskie has essentially had to incorporate Plaintiffs’ unredacted, unfiled brief into his decisions by reference. ([ECF 1061, p. 6 n.4](#) (stating “Much of the information presented by Plaintiffs has been redacted from the version of the brief that is on the public docket in this matter. This Order treats the significant unredacted information in a nondescript manner so as to allow this Order to be placed on the public docket.”))). In the decision under review, Special Master Vanaskie revealed as much of the record as he felt justified given ZHP’s insistence that it remain off the docket. Very telling, ZHP subsequently waived the confidentiality of most of these documents. ([ECF 1392](#)). Putting this aside, the decision is well-supported.

ZHP cites a total of five cases—all but one unpublished—in support of its focus on its misunderstanding of the “apex doctrine,” to the extent it exists. In the first case, *United States ex rel. Galmines v. Novartis Pharm. Corp.*, No. CV 06-3213, 2015 WL 4973626, at \*1 (E.D. Pa. Aug. 20, 2015), the court acknowledged that the “apex doctrine does not represent an exception to the rule that a party seeking to quash a subpoena bears the ‘heavy burden’ of demonstrating that the subpoena represents an undue burden.” *Id.* at 2 (citing *Frank Brunckhorst Co. v. Ihm*, No. MISC. 12–0217, 2012 WL 5250399, at \*4 (E.D. Pa. Oct. 23, 2012)). Relying on an unpublished trial court case from North Carolina, the Court nevertheless held that the “apex doctrine does ... apply a rebuttable presumption that a high-level official's deposition represents a significant burden upon

the deponent and that this burden is undue absent the two factors set forth in the apex doctrine, which go to the lack of a more convenient, less burdensome, and less expensive alternative.” *Id.* (citing *Performance Sales & Mktg. LLC v. Lowe's Companies, Inc.*, No. 5:07–CV–00140–RLV, 2012 WL 4061680, at \*3–4 (W.D.N.C. Sept. 14, 2012), *overruled on other grounds*, *Fourth Estate Public Benefit Corp. v. Wall-Street.com, LLC*, — U.S. —, 139 S. Ct. 881 (2019)). As established on this record, the witness’s direct involvement and knowledge overcomes ZHP’s efforts to paint him as an unnecessary witness, thus ZHP cannot meet its burden to obtain a protective order.

Of note, **ZHP does not cite a District of New Jersey case adopting this presumption, and as recognized by the Sixth Circuit, Rule 26 is the touchstone and does not support such a presumption.** Moreover, the facts and posture presented in *Galmines* are night and day from this case. There, the plaintiff offered only two documents in support of her need for the deposition of a CEO:

In support of his position, Mr. Galmines has filed with the Court a PowerPoint slide that Mr. Gorsky allegedly reviewed. The slide displays the percentage of Elidel sales for off-label uses. Mr. Galmines has also submitted an email from Mr. Gorsky to a business associate in which Mr. Gorsky recommends editing that PowerPoint slide by changing the phrase “off-label sales” to “other sales.”

**This allowed the court to easily distinguish the case from *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Products Liab. Litig.*, No. 2:13–MD–02436, 2014 WL 3035791, at \*3 (E.D. Pa. July 1, 2014), “where Judge Stengel denied a motion to quash because ‘documents, which have been produced by the defendants during discovery, show very clearly that [the high-ranking executive] was actively involved in decision making regarding the marketing and product development of Tylenol products.’”** *Galmines*, 2015 WL 4973626, at \*2. This case is clearly more akin to *In re Tylenol* in that Plaintiffs have cited and described dozens of

documents and compelling deposition testimony, establishing Mr. Chen's integral role in the matters at issue here.

Second, ZHP cites, *George v. Pennsylvania Tpk. Comm'n*, No. 1:18-CV-766, 2020 WL 2745724, at \*3 (M.D. Pa. May 27, 2020). That case concerned an ethnic discrimination lawsuit where the plaintiff asked to depose the Pennsylvania Turnpike Commission's CEO only after the fact discovery deadline had expired. *Id.* at \*1. The court denied this request primarily because "we deem the request to be untimely." *Id.* at \*3. Importantly, the court never mentioned, let alone relied on, a "presumption" against "apex witnesses."

ZHP's third case is a decision authored by Judge Schneider, *Younes v. 7-Eleven, Inc.*, No. CV 13-3500 (RMB/JS), 2015 WL 12844446, at \*2 (D.N.J. Aug. 19, 2015). Judge Schneider has previously concluded that any "apex doctrine" is inapplicable to Mr. Chen and ordered his deposition, as he was intimately involved in the events at issue. ([12/22/2020 Tr. 40:4-5, 44:2-8](#)). *Younes* is easily distinguished here, as that decision concerned the plaintiffs' second motion for the depositions of 7-Eleven's CEO and former executive vice president. *Id.* at \*1-2. In deciding the first motion, Judge Schneider said, "If the record is going to [stay] as it is in the motion, you're not going to get these depositions. You haven't shown the Court that these witnesses have personal and unique information." *Id.* \*2. On their second motion, "plaintiffs[] ...essentially rehashe[d] the same arguments in plaintiffs' first motion." *Id.* Here, the shoe is on the other foot. Judge Schneider ordered the deposition of Mr. Chen, having found him to have direct involvement and information. Thus, *Younes* supports denial of ZHP's motion.<sup>7</sup>

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<sup>7</sup> In *Younes*, Judge Schneider noted that "[t]he parties do not dispute the applicable standard to apply to decide if high-ranking corporate executives may be deposed," suggesting that the Court would otherwise have considered counter arguments. 2015 WL 12844446, at \*2.

Fourth, *Reif v. CNA*, 248 F.R.D. 448 (E.D. Pa. 2008), concerned a husband's and wife's age discrimination suit against their former employer for their 2006 and 2007 terminations, respectively. The pair sought to depose the defendant's CEO concerning his 2002 statement that "We need to get kids in here." *Id.* at 449. The court found that the record "reveal[ed] no connection between [the CEO's] 2002 statement and the decision to terminate [the husband]." <sup>8</sup> Here, Plaintiffs have provided the Court with a record establishing Mr. Chen's role at the linchpin of the ZHP Organization and its contaminated valsartan. (*See supra*). *Reif* is thus entirely distinguishable.

*Ciarrocchi v. Unum Grp.*—ZHP's fifth case—is even more inapposite, and supports Plaintiffs' position to the extent relevant here. No. CV 08-1704 (JBS/AMD), 2009 WL 10676631, at \*3 (D.N.J. Aug. 27, 2009). It is worth noting that this case involved a pro se plaintiff's suit "seek[ing] to vacate the [parties' prior] settlement, reinstate the disability insurance policy, and re-establish disability payments." *Id.* at \*1. Like *Younes*, the plaintiff previously lost a motion to compel the depositions of the defendant's CEO and COO. *Id.* at \*2. Instead, the court ordered the deposition of another employee "that was involved in handling [the p]laintiff's claim." *Id.* However, the plaintiff never took that deposition and instead filed another motion to depose the defendant's CEO. *Id.* During a status conference regarding this second motion, the court thought that the parties had agreeably resolved this dispute and allowed for the deposition of an employee besides the CEO, but the plaintiff ultimately filed a third motion to compel the deposition of the CEO and COO. *Id.* The pro se plaintiff simply argued "that he requires these depositions because he seeks to obtain information regarding Defendant's general practices and policies for settling claims." *Id.* The court held that "[f]ederal courts have permitted the depositions of high level

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<sup>8</sup> The Court focused its analysis on the husband.

executives when conduct and knowledge at the highest corporate levels of the defendant are relevant in the case.” *Id.* at \*3 (quoting *In re Bridgestone/Firestone, Inc. Tires Prod. Liab. Litig.*, 205 F.R.D. 535, 536 (S.D. Ind. 2002)). However, “[t]he Court finds that Plaintiff fails to demonstrate at this time that either [the CEO] or [COO] have unique knowledge of relevant facts in this case.” *Id.* Here, the record shows Mr. Chen has unique knowledge of facts relevant to Plaintiffs’ cases, so this case supports Plaintiffs’ position. (*See supra*).

### **CONCLUSION**

For the foregoing reasons, ZHP has not met its burden of showing that Baohua Chen’s deposition would work a clearly defined and serious injury. The Court should therefore deny ZHP’s motion to vacation Special Master Vanaskie’s order denying its motion for a protective order precluding his deposition.

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Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on August 2, 2021, a true and correct copy of the foregoing was filed and served upon all counsel via operation of the CM/ECF system for the United States District Court for the District of New Jersey.

/s/ Adam M. Slater

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